

TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE



FISCAL MEMORANDUM

SB 97 - HB 86

March 9, 2015

SUMMARY OF ORIGINAL BILL: Requires any third-party logistics provider that warehouses or coordinates logistics for controlled substances to obtain an annual registration with the Board of Pharmacy and any appropriate occupational or professional licensing board. Previously, these logistic providers were regulated by the Board as wholesalers. Adds definitions related to the wholesale and distribution of drugs to match federal law.

FISCAL IMPACT OF ORIGINAL BILL:

Other Fiscal Impact - The Board of Pharmacy will now regulate third-party logistics providers separately from wholesalers. Based on information provided by the Board, it does not intend to change any current fee levied against such logistics providers; however, in the case any fee amount is changed, there will be a corresponding change to fee revenue collections.

SUMMARY OF AMENDMENT (003689): Makes various changes to definitions provided in the original bill. Adds and defines "outsourcing facility." Specifies that transfers and sales of drugs or devices from one licensed pharmacy to another do not constitute distribution or wholesale distribution of drugs or devices.

FISCAL IMPACT OF BILL WITH PROPOSED AMENDMENT:

Unchanged from the original fiscal note.

Assumptions for the bill as amended:

- Based on information provided by the Department of Health, this legislation intends to make state law reflect requirements passed in the Federal Drug Quality and Security Act (DQS). The DQS was signed into law on November 27, 2013.
- Title II of the DQS is entitled the "Drug Supply Chain Security Act" and was passed for the purpose of identifying and tracing certain prescription drugs as they are distributed in the United States. Drug manufacturers, wholesale drug distributors, repackagers, and dispensers will cooperate with the FDA to develop a new electronic, interoperable system to identify and trace prescription drugs. All requirements in this Act will be enacted within ten (10) years of its passage.
- Currently, third-party logistics providers are regulated as drug wholesalers by the state. After passage of the DQS, combining regulation of pure wholesalers and logistics

SB 97 - HB 86

providers is forbidden by federal law. The provisions of the bill will not significantly affect the current oversight and regulatory operations of the Board of Pharmacy.

- Based on information provided by the Department of Health, third-party logistics providers will not be charged any registration or licensing fee that is different than current fees levied on wholesalers; therefore, fee revenue collections will not change.
- Pursuant to Tenn. Code Ann. § 4-29-121, all health related boards are required to be self-supporting over any two-year period.
- The Board of Pharmacy had an annual surplus of \$296,813 in FY12-13, an annual deficit of \$66,136 in FY13-14, and a cumulative reserve balance of \$1,160,083 on June 30, 2014.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

A handwritten signature in dark ink, reading "Jeffrey L. Spalding". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Spalding" clearly legible.

Jeffrey L. Spalding, Executive Director

/jdb